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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,843	06/27/2003	Ashok V. Joshi	001234CIP	8472

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EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/607,843	Applicant(s) JOSHI, ASHOK V.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

No Information Disclosure Statement has been received in association with this application. Claims 1 – 24 are pending in this action.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 requires an effervescent agent associated with the first beneficial agent. However, parent claim 1 requires that the particle core consists essentially of a core component and a beneficial agent, wherein the possible core components are specified. None of the core components are effervescent materials, and an effervescent material is considered to be a functional component of the composition. Instant “consisting essentially of” language in the parent claim does not permit the inclusion of another functional component. Accordingly, the independent claim fails to limit the parent since it is in fact broader in scope than the parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

With regard to claim 2, the claim recites “the beneficial agent is associated with an effervescent material”. The disclosure gives no guidance as to what effervescent materials are appropriate for use with the invention, nor is there even one example of a beneficial agent associated with an effervescent material. Accordingly, it is not clear that applicant actually had possession of a beneficial agent associated with an effervescent material as of the filing date of the application. Claim 1 is rejected under this statute since there is at least one embodiment thereof, illustrated by claim 2, which is inadequately described.

With regard to claim 24, the claim recites a process for increasing the exposed surface area of a beneficial agent. There is nothing in the disclosure as originally filed to support the notion that the process steps, as claimed, actually accomplish the claimed increasing of exposed surface area. For example, there is no showing in the specification that the claimed increasing of exposed surface area is achieved. The artisan, accordingly, would not recognize that the method, as claimed, actually increased the surface area of the beneficial agent. Accordingly, the artisan would doubt that Applicant had possession of a method that increased the exposed surface as of the filing date of the application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing. It is unclear whether the composition of the claim has only one core component with one beneficial agent adsorbed thereon, or if the composition has three components, each marked by one of the first three dashes in the list after comprising. Also, the phrase of the claim beginning on line 13 seems to be part of a list of components, since it begins with a dash, but this part of the claim seems to be a description of one of the components of the composition. Also the claim recites “less than approximately 10 M²/gm”. The claim is indefinite since it is not clear how close to 10 M²/gm qualifies as approximately as claimed. As such, the artisan would not understand the metes and bounds of the claim. Clarification is requested.

Claim 2 recites “associated with an effervescent material”. It is not clear what is meant by “associated with”, and the specification provides no guidance. For example, this phraseology may mean that the beneficial agent is effervescent, or that the composition additionally comprises an effervescent material, or that the beneficial agent is chemically bound to an effervescent material. Clarification is requested. For the purposes of a compact prosecution, Examiner will presume that applicant intended to mean that the composition additionally comprises an effervescent material.

Claims 3 and 4 recite "comprises a diameter". It is unclear how a particle can comprise a diameter, since a diameter is not a physical object. For the purpose of compact prosecution, Examiner presumes that applicant meant that the material comprises components that have a diameter of the ranges specified. Clarification is requested.

Claims 5, 6, 7, 9, 17 and 21 recite improper Markush language.

Claim 8 recites "fabricated from an antibacterial agent". It is unclear if this requires that the core be an antibacterial agent, include an antibacterial agent, or merely requires that an antibacterial agent is used in the process of making. Further, it is not clear if applicant intends a product-by-process claim. Clarification is requested.

Claim 10 recites "a second beneficial associated with at least a first portion of the first beneficial agent". It is not clear what is meant by "associated with", and the specification provides no guidance. For example, this phraseology may mean that the composition additionally comprises the second beneficial agent, or that the first beneficial agent is chemically bound to the second. Clarification is requested. For the purposes of a compact prosecution, Examiner will presume that applicant intended to mean that the composition additionally comprises a second beneficial agent.

With regard to claim 12, it is unclear how a tertiary agent can be applied to the surface of the first or second beneficial agents, if the first and second agents are not present as particles, bead, or granules, but are instead adsorbed onto a core. Clarification is requested.

Claim 13 recites the limitation "the component" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites "less than approximately $10 \text{ M}^2/\text{gm}$ ". The claim is indefinite since it is not clear how close to $10 \text{ M}^2/\text{gm}$ qualifies as approximately as claimed. As such, the artisan would not understand the metes and bounds of the claim. Claim 14 also recites "a stoichiometrically stable material". The meaning of this term is unclear, and the specification provides no guidance. In addition, the claim is confusing since it is not clear how many components are present in the claimed composition. There are four listed items after the recitation of "comprising", thus implying four components, however, from the wording of the claim, it seems that there may only be two required components, a core and a beneficial agent. Clarification is requested.

Claim 15 is confusing. The claim recites "less than approximately $10 \text{ M}^2/\text{gm}$ ". The claim is indefinite since it is not clear how close to $10 \text{ M}^2/\text{gm}$ qualifies as approximately as claimed. As such, the artisan would not understand the metes and bounds of the claim. Also, it is not clear how many process steps are required in the claimed process. It seems that the second listed "step", beginning on line 21 of the page, is not a process step. Clarification is requested.

Claim 17 recites the limitation "absorbing" in claim 15. There is insufficient antecedent basis for this limitation in the claim. Note that claim 15 recites "adsorbing", however, "absorbing" and "adsorbing" are different processes.

Claim 23 recites "associating the second beneficial agent with at least a portion of the first beneficial agent". It is unclear what is involved in the "associating" recited in

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the claim. Clarification is requested. For the purpose of compact prosecution, Examiner is interpreting this claim to mean that the second beneficial agent is added to the composition comprising the first beneficial agent.

With regard to claim 24, it is unclear how many process steps are required in this claim. There are three items listed after the recitation "comprising the steps of", however, not all of these items appear to be process steps. Clarification is requested.

The remaining claims are rejected as dependant on an indefinite claim, and thus incorporating the indefinite limitations thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 – 7, 9, 13, 14, 15, 17 – 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,758,424 to Denick et al.

Denick teaches a medicament adsorbate made of particles which comprise aluminum oxide and a pharmaceutical agent (abstract). The particle sizes are commensurate with those of instant claims (col. 3, lines 30 – 37). Several methods of preparation are also disclosed, wherein the aluminum oxide is provided to a solution of the medicament and the particles are later dried of solvent, or where the two components are blended (col. 4). In either case, the medicament is adsorbed onto the particles. The surface area is not specifically disclosed, however, since the particles of

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the art are made of the same material as those of instant claims and have the same particle sizes, it is deemed to be inherent that the surface area is the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, and 3 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over DERWENT-ACC-NO: 1973-72532U (Derwent).

Derwent teaches activated aluminum oxide particles and suggests use of the same to adsorb pharmaceuticals. Aluminum oxide is substantially inert and hygroscopic.

Derwent does not disclose the diameter of the particles, nor does Derwent require that the particles be used with pharmaceuticals.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the particles with pharmaceuticals, since doing so is merely following the suggestion of Derwent. The person of ordinary skill in the art would be motivated to do so, since Derwent suggests it, and would enjoy a reasonable expectation of success. The expected result would be alumina particles with adsorbed drugs.

Absent a showing of an unexpected result, it would be further obvious to optimize the particle size as appropriate, with the motivation being to achieve the best possible result for the desired application. Since doing so is within the skill of the art, the artisan would enjoy a reasonable expectation of success. The expected result would be alumina particles with adsorbed drugs where the particle size was optimized for the desired use.

Claims 8, 10 – 12, 16, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denick.

Some of the teachings of Denick are discussed above.

Denick also teaches that a mixture of several therapeutic agents may be adsorbed onto the particles, and anti-bacterials are among the suggested agents (paragraph bridging col.'s 3 and 4). Denick further teaches that it is important to blend the particles thoroughly until they are uniform. (col. 2, lines 30 – 37). The artisan would understand this as a suggestion to mill the particles.

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to include several therapeutic agents, including antibacterials, and to mill the particles. The motivation for doing so is that these manipulations are suggested by Denick. Thus, the artisan would carry out these manipulations in order to follow the suggestions of the art. Accordingly, the skilled artisan would enjoy a reasonable expectation of success.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Denick in view of US 4,336,604 to Mitra.

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Some of the teachings of Denick are discussed above. Denick also teaches that a preferred dosage form for the composition is a lozenge (col. 5, line 51 – col. 7, line 34).

Mitra teaches that sodium bicarbonate is a preferred beneficial agent in lozenges that are used as antacids (abstract). Sodium bicarbonate is also an effervescent material.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use sodium bicarbonate as a beneficial agent in the dosage form of Denick. The motivation to do so is to effectively treat acid with the lozenge of Denick in addition to the action of the first medicament. Since Denick teaches that the dosage form of the invention can be used with a variety of beneficial agents and combinations of beneficial agents, and that the dosage form is preferably a lozenge, the artisan would have a reasonable expectation of success. The expected result would be a lozenge according to Denick that also comprised the effervescent agent sodium bicarbonate.

Conclusion


No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1615

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